

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/
FENFLURAMINE/DEXFENFLURAMINE)
PRODUCTS LIABILITY LITIGATION

MDL NO. 1203

THIS DOCUMENT RELATES TO:

SHEILA BROWN, et al.

v.

CIVIL ACTION NO. 99-20593

AMERICAN HOME PRODUCTS
CORPORATION

2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9086

Bartle, J.

June 6, 2013

Margaret R. Williams ("Ms. Williams" or "claimant"), a class member under the Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth, Inc.¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claims for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Richard I. Williams, claimant's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In October, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Robert N. Notske, M.D., F.A.C.C., F.A.C.P. Based on an echocardiogram dated June 5, 2002, Dr. Notske attested in Part II of claimant's Green Form that Ms. Williams suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and a reduced

3. (...continued)

medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

ejection fraction in the range of 50% to 60%.⁴ Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$453,042.⁵

In the report of claimant's echocardiogram, the reviewing cardiologist, Susan J. Alexander, M.D., F.A.C.C., stated that claimant had "2+ mitral regurgitation," which she measured at 24%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In February, 2004, the Trust forwarded the claim for review by Kevin S. Wei, M.D., one of its auditing cardiologists. In audit, Dr. Wei concluded that there was no reasonable medical basis for Dr. Notske's finding that claimant had moderate mitral regurgitation. Dr. Wei explained, "Multiple measurements of different [mitral] RJAs = 1.9, 2, 1.7 cm². LAA = 17 cm². [Mitral] RJA/LAA all <20%."

4. Dr. Notske also attested that claimant suffered from moderate aortic regurgitation and New York Heart Association Functional Class II symptoms. These conditions are not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

Based on Dr. Wei's finding that claimant did not have moderate mitral regurgitation, the Trust issued a post-audit determination denying this claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁶ In contest, Ms. Williams submitted a declaration of Dr. Notske wherein he stated:

The Auditing Cardiologist found "mild regurgitation of <20%, measuring different locations." Different jet areas would be a normally expected finding. But the placement of the cursor is a subjective phenomenon, and is part of the reason for the variation in these figures. On the patient's tape, there is a well-demarcated area of the Left Atrium and the Mitral Regurgitation jet. This definitely fits the accepted Matrix criteria for Moderate Regurgitation. The Auditor's measurements are not even near the measurement of this well demonstrated view. Therefore, I believe the patient's degree of Mitral Regurgitation, as Moderate, is well proven.

The Trust then issued a final post-audit determination, again denying this claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to this claim.

Show Cause why this claim should be paid. On May 20, 2005, we issued an Order to Show Cause and referred the matter to the Special Master for further proceedings. See PTO No. 5239 (May 20, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on August 23, 2005.

In support of her claim, Ms. Williams argues that there is a reasonable medical basis for Dr. Notske's representation that she had moderate mitral regurgitation because that finding was corroborated by Dr. Alexander, who performed claimant's echocardiogram as part of the Trust's Screening Program.⁷ In addition, Ms. Williams contends that Dr. Notske followed the guidelines of Weyman while the auditing cardiologist "subjectively measured jet areas that were not even close in proximity to a well-demarcated area of left atrium and mitral regurgitation jet."

In response, the Trust argues that Dr. Notske's declaration does nothing more than repeat his Green Form representation that claimant had moderate mitral regurgitation. In addition, the Trust argues that Dr. Wei properly evaluated

7. See Settlement Agreement § IV.A.1.a. (Screening Program established under the Settlement Agreement).

claimant's level of mitral regurgitation, including providing specific measurements of the RJA/LAA ratio.⁸

In September, 2005, claimant submitted a second completed Green Form to the Trust signed by her attesting physician, Dr. Notske. Based on an echocardiogram dated June 14, 2005, Dr. Notske attested in Part II of claimant's Green Form that Ms. Williams suffered from moderate mitral regurgitation and had surgery to repair or replace the aortic and/or mitral valve(s) after use of Pondimin® and/or Redux™.⁹ Based on such findings, claimant would be entitled to Matrix A-1, Level III benefits in the amount of \$702,666.¹⁰

As the Trust does not contest claimant's entitlement to Level III benefits, the only issue in this second claim is whether claimant is entitled to payment on Matrix A-1 or Matrix B-1. Specifically, the Settlement Agreement requires the payment of reduced Matrix Benefits to a claimant who is diagnosed with

8. The Trust also contends that the opinion of Dr. Notske should be excluded because it is not verified. We disagree. While the Audit Rules allow for the submission of verified expert opinions, it does not preclude the submission of expert opinions that are not verified. See Audit Rule 18(b).

9. Dr. Notske also attested that claimant suffered from moderate aortic regurgitation, an abnormal left atrial dimension, a reduced ejection fraction in the range of 50% to 60%, and New York Heart Association Functional Class II symptoms. These conditions are not at issue in this claim.

10. Under the Settlement Agreement, a claimant is entitled to Level III benefits if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." Settlement Agreement § IV.B.2.c.(3)(a).

mild mitral regurgitation¹¹ by an echocardiogram, like claimant's June 5, 2002 here, which was performed between the commencement of Diet Drug use and the end of the Screening Period. See Settlement Agreement § IV.B.2.d.(2)(a).

In March, 2008, the Trust forwarded the claim for review by Craig M. Oliner, M.D., one of its auditing cardiologists. Because claimant's June 14, 2005 echocardiogram of attestation was performed after the end of the Screening Period established under the Settlement Agreement, claimant also had to establish her eligibility for Matrix Benefits. See generally Settlement Agreement § IV.B.1.a. In PTO No. 3192 at 3 (Jan. 7, 2004), we stated, "Experiencing left sided valvular heart disease is of no moment unless the claimant also passes muster under § IV.B.1.a.". Accordingly, Dr. Oliner reviewed claimant's June 5, 2002 echocardiogram, which previously was provided by claimant to the Trust in connection with her claim for Level II Matrix Benefits. Dr. Oliner concluded that there was no reasonable medical basis for Dr. Notske's conclusion that claimant's June 5, 2002 echocardiogram demonstrated moderate mitral regurgitation. Dr. Oliner stated that:

There is mild [mitral regurgitation], with a RJA/LAA substantially less than 20%. The single measured RJA is a freeze frame and does not represent [mitral regurgitation].

11. Under the Settlement Agreement, mild mitral regurgitation is defined as "(1) either the RJA/LAA ratio is more than five percent (5%) or the mitral regurgitant jet height is greater than 1 cm from the valve orifice, and (2) the RJA/LAA ratio is less than twenty percent (20%)." Settlement Agreement § I.38.

It is low velocity non [mitral regurgitant] signal.

Based on Dr. Oliner's finding that claimant's June 5, 2002 echocardiogram demonstrated only mild mitral regurgitation, the Trust issued a post-audit determination that Ms. Williams was entitled only to Matrix B-1, Level III benefits. Pursuant to the Audit Rules, claimant contested this adverse determination.¹² In contest, claimant argued that Dr. Alexander and Dr. Notske employed the Feigenbaum and Weyman standards required by the Settlement Agreement because they incorporated lower flow spray while Dr. Oliner did not. In support of this argument, claimant submitted another Declaration from Dr. Notske, which stated, in relevant part, that Feigenbaum requires the measurement of the "maximum turbulent flow area" rather than "the most representative jet." In addition, Dr. Notske noted, "This measurement is to include the 'lower flow spray' or 'the non-high velocity flow that surrounds the mosaic turbulent blood.'" ¹³

Although not required to do so, the Trust forwarded the claim to Dr. Oliner for a second review. Dr. Oliner submitted a declaration wherein he confirmed his conclusion that claimant's

12. As this claim was placed into audit after December 1, 2002, there is no dispute that the Audit Rules contained in PTO No. 2807 also apply to this claim.

13. Claimant also asserted that the conclusion of moderate mitral regurgitation is further supported by the fact that claimant underwent mitral valve repair surgery. The mere occurrence of mitral valve surgery, however, does not entitle a claimant to Matrix A-1 Level II benefits. Rather, a claimant is only entitled to such benefits in the absence of any applicable reduction factor.

June 5, 2002 echocardiogram revealed only mild mitral regurgitation. Dr. Oliner explained that Feigenbaum "does not direct that proper measurement of mitral regurgitation *must* include low velocity flow". Dr. Oliner also pointed to Feigenbaum's statement that "some data suggest that measuring the turbulent mosaic pattern is more accurate than including the non-high velocity flow that surrounds the mosaic turbulent blood."

The Trust then issued a final post-audit determination, again determining that Ms. Williams was entitled only to Matrix B-1, Level III benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why this claim should be paid. On August 21, 2008, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 7925 (Aug. 21, 2008).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on November 25, 2008, and claimant submitted a sur-reply on December 10, 2008.

In support of her claim, claimant reasserts the arguments that she made during contest. In addition, claimant

submitted another declaration from her attesting physician, Dr. Notske, wherein he reiterated his interpretation of the Feigenbaum text. Dr. Notske also commented, in relevant part, that:

16. In Paragraph 12 of his Declaration, Dr. Oliner gets around Feigenbaum's protocol by claiming the freeze-frame image does not show mitral valve regurgitation at all, but only the lower flow spray. Contrary to the averment of Dr. Oliner, the freeze frame shows a regurgitant jet. A mitral valve regurgitant jet is evidenced on the echocardiogram by a multicolored turbulent jet and is seen easily in the left atrium. Feigenbaum, *Echocardiography*, [at] 251. What I identified on the June 5, 2002, freeze-frame image (and other images) was a mitral regurgitant jet. The freeze-frame image clearly showed the jet occupying a well-demarcated area of the left atrium.
17. Although the Trust Auditor may reach a different conclusion from me and the Trust Screening Cardiologist, there is a reasonable medical basis to support the finding of moderate mitral regurgitation.

In response, the Trust asserts that the attesting physician improperly relied upon a single regurgitant jet, which consisted only of low velocity flow and was not representative of mitral regurgitation. The Trust argues that claimant misinterprets the Feigenbaum text, which suggests that mitral regurgitation should be representative. Finally, the Trust contends that claimant failed to "identify a holosystolic jet of

mitral regurgitation that appears in consecutive frames and meets the 20% ratio required by the Settlement Agreement."

Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor¹⁴ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Records and Technical Advisor Report associated with these claims are now before the court for final determination. See id. Rule 35.

The Technical Advisor, Dr. Abramson, reviewed claimant's June 5, 2002 echocardiogram and concluded that there was no reasonable medical basis for Dr. Notske's Green Form representation that claimant had moderate mitral regurgitation. Specifically, Dr. Abramson observed:

In reviewing the transthoracic echocardiogram from 6/05/02, my visual estimate is that there is only mild mitral regurgitation. I measured the mitral regurgitant jet and the left atrial area in the same frame in five

14. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F. 2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

representative cardiac cycles. My measurements for mitral regurgitant jet area/left atrial area are $1.85 \text{ cm}^2/19.91 \text{ cm}^2$, $1.20 \text{ cm}^2/19.50 \text{ cm}^2$, $1.56 \text{ cm}^2/17.70 \text{ cm}^2$, $1.13 \text{ cm}^2/19.24 \text{ cm}^2$, and $1.67 \text{ cm}^2/20.40 \text{ cm}^2$. These ratios are 9%, 6%, 9%, 6%, and 8%, all of which are considerably less than 20% which is consistent with mild mitral regurgitation. The most impressive finding on this echo was a massively dilated right ventricle which also was noted on a previous echo report from 1996.

The frozen image of the mitral regurgitation tracing on the tape included low velocity, non-regurgitant flow. Because of the inclusion of the non-regurgitant flow, the RJA/LAA was incorrectly traced as $4.06 \text{ cm}^2/17.5 \text{ cm}^2=23\%$. The jet in the frozen frame was not shown in real-time on the tape which makes it difficult to determine the actual level of regurgitation in this cardiac cycle.

In summary, it would be impossible for a reasonable echocardiographer to interpret this severity of mitral regurgitation as moderate. There is no reasonable medical basis for the Attesting Physician's claim that this claimant has moderate mitral regurgitation. Margaret R. Williams has only mild mitral regurgitation.

In response to the Technical Advisor Report, claimant argues that the Technical Advisor did not properly follow the Feigenbaum or Weyman texts, which direct that the maximum regurgitant flow area be measured.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. The Settlement Agreement requires that a claim for benefits be reduced if certain medical conditions are present. See Settlement Agreement § IV.B.2.d. In this case, the claims of Ms. Williams for damage to her mitral

valve must be reduced to Matrix B-1 if she had mild mitral regurgitation as demonstrated by an echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period. Settlement Agreement § IV.B.2.d.(2)(a).

First, we reject claimant's argument that the still-frame images claimant submitted demonstrate a reasonable medical basis for the attesting physician's finding that Ms. Williams had moderate mitral regurgitation. Dr. Abramson observed that "[t]he jet in the frozen frame was not shown in real-time on the tape which makes it difficult to determine the actual level of regurgitation in this cardiac cycle." In addition, Dr. Oliner determined that the "freeze frame ... does not represent [mitral regurgitation]."¹⁵

Although still frames are necessary to determine a claimant's level of mitral regurgitation, they alone are not sufficient. See PTO No. 6997 at 7 (Jan. 26, 2007). Indeed, we have determined that "[o]nly after reviewing multiple loops and still frames can a cardiologist reach a medically reasonable assessment as to whether the twenty percent threshold for

15. According to claimant's pharmacy records, claimant began taking Diet Drugs at least as early as June 1996. The Show Cause Record also contains a report for an echocardiogram conducted on October 11, 1996. In the echocardiogram, the reviewing cardiologist, Patrick A. Barker, M.D., concluded that claimant had mild mitral regurgitation. Thus, in addition to the June 5, 2002 echocardiogram, there is an additional echocardiogram, which diagnosed claimant with mild mitral regurgitation between the commencement of Diet Drug use and the end of the Screening Period. This additional echocardiogram further supports the conclusion that claimant is only entitled to Matrix B-1 benefits.

moderate mitral regurgitation has been achieved.'" Id. (quoting PTO No. 2640 at 9). As stated previously, moderate mitral regurgitation is present where the RJA/LAA in any apical view is equal to or greater than 20%. See Settlement Agreement § I.22. Based on Dr. Abramson's specific determination that claimant's RJA/LAA ratio was "considerably less than 20%," these still-frame images alone do not provide a reasonable medical basis for Dr. Notske's representation that claimant suffered from moderate mitral regurgitation.

Claimant's argument that the presence of moderate mitral regurgitation at any point in the study dictates that it is present throughout the study is misplaced. We previously have held that "[f]or a reasonable medical basis to exist, a claimant must establish that the findings of the requisite level of mitral regurgitation are representative of the level of regurgitation throughout the echocardiogram." PTO No. 6997 at 11 (Feb. 26, 2007); see also In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liab. Litig., 543 F.3d 179, 187 (3d Cir. 2008). "To conclude otherwise would allow claimants who do not have moderate or greater regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement." PTO No. 6997 at 11.

We also disagree with claimant that "lower flow spray" is considered mitral regurgitation. We have consistently held that conduct "beyond the bounds of medical reason" can include characterizing low velocity flow as mitral regurgitation. PTO

No. 2640 at 11-13, 15, 22, 26. We have further found that "[o]n a color flow Doppler echocardiogram, mitral regurgitation will thus display as a high velocity, mosaic blue/green teardrop shaped jet that borders the mitral valve leaflets and expands into the left atrium throughout at least a portion of systole." Id. at 10-11 (footnote omitted). There is nothing to indicate that including low velocity flow as mitral regurgitation is permissible under the Settlement Agreement.

Significantly, claimant does not contest that her physicians included low velocity flow as mitral regurgitation in determining that she had moderate mitral regurgitation. Moreover, Dr. Oliner determined in audit, and Ms. Williams does not adequately dispute, that her attesting physician's finding of moderate mitral regurgitation was based on incorrectly characterizing low velocity flow as mitral regurgitation, resulting in an erroneous diagnosis of moderate mitral regurgitation. The Technical Advisor, Dr. Abramson, similarly concluded that the single frame identified by claimant's attesting physician included "low velocity, non-regurgitant flow." Such an unacceptable practice by claimant's attesting physician cannot provide a reasonable medical basis for the resulting diagnosis of moderate mitral regurgitation.

Finally, to the extent claimant argues that she is entitled to Matrix Benefits because a cardiologist who participated in the Screening Program corroborated the attesting physician's representation of moderate mitral regurgitation, such

argument is misplaced. See Settlement Agreement § IV.A. The Settlement Agreement clearly provides that the sole benefit that an eligible class member is entitled to receive based on an echocardiogram performed in the Screening Program is a limited amount of medical services or a limited cash payment:

All Diet Drug Recipients in Subclass 2(b) and those Diet Drug Recipients in Subclass 1(b) who have been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period, will be entitled to receive, at the Class Member's election, either (i) valve-related medical services up to \$10,000 in value to be provided by the Trust; or (ii) \$6,000 in cash.

Id. § IV.A.1.c. Thus, by the plain terms of the Settlement Agreement, a Screening Program echocardiogram does not automatically entitle a claimant to Matrix Benefits.

Indeed, this conclusion is confirmed by the Settlement Agreement provisions concerning claimants eligible for Matrix Benefits. Specifically, claimants receiving a diagnosis of FDA Positive or mild mitral regurgitation merely become eligible to seek Matrix Benefits. See id. § IV.B.1. Further, adopting claimant's position would be inconsistent with Section VI.E. of the Settlement Agreement, which governs the audit of claims for Matrix Benefits, as well as this Court's decision in PTO No. 2662, (Nov. 26, 2002), which mandated a 100% audit for all claims for Matrix Benefits. See PTO No. 2662 at 13 (Nov. 26, 2002). Nothing in the Settlement Agreement supports the conclusion that a favorable Screening Program echocardiogram

for purposes of Fund A Benefits results in an immediate entitlement to Matrix Benefits.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that her June 5, 2002 echocardiogram demonstrates moderate mitral regurgitation. The June 5, 2002 echocardiogram only demonstrates mild mitral regurgitation. Therefore, we will affirm the Trust's denial of the claim of Ms. Williams for Matrix A-1, Level II benefits and the derivative claim submitted by her spouse. We also will affirm the denial of the claim of Ms. Williams for Matrix A-1, Level III benefits and the derivative claim of her spouse.